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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,327	05/15/2002	Jay M Meythaler	UAB-15102/22	3596

25006 7590 07/28/2005

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EXAMINER

MITCHELL, GREGORY W

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,327

Applicant(s)

MEYTHALER ET AL.

Examiner

Gregory W. Mitchell

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-7 and 29-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This Office Action is in response to the Remarks and Amendments filed June 01, 2005. Claims 1, 29, 36 and 41 have been amended. Claims 1, 4-7 and 29-41 are pending and are examined herein.

Applicant's amendments with regard to the 35 USC 112(2) rejection of the Office Action dated February 18, 2005 are sufficient to overcome said rejection. All rejections of the previous Office Action are hereby withdrawn. The following rejections now apply.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 29, 36, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "substituted form" is indefinite. The phrase "substituted form" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what compounds are intended to be encompassed by the phrase "substituted form". "Substituted form" is defined by the specification as only having "one ore more substituents". Does that mean that the claim is intended to encompass all structures in which a salicylate moiety may be found? Do these other structures have to have non-steroidal anti-inflammatory activity?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-7, 29, 30, 32-36, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grilli et al. (WO 98/20864) in view of Bakhshi et al. (*Journal of Neuro-Oncology*, 26, 133-9).

Grilli et al. teaches the treatment of Alzheimer's disease through the use of NSAIDs (Abstract). Sodium salicylate and salicylamide are specifically taught as NSAIDs useful in the invention disclosed therein (p 3). Neuronal damages (i.e. neurotrauma or neuronal injury) related to Alzheimer's disease are specifically taught as treatable by the NSAIDs disclosed therein (p 6). Generally, cranial and spinal traumas are also taught to be treatable by the methods disclosed (p 6). Grilli et al. lacks a specific teaching of the claimed mode of administration.

Bakhshi et al. teaches the administration of CNS drugs via intrathecal catheter. Such administration is taught to alleviate adverse systemic effects, peripheral metabolism of centrally acting drugs, inadequate blood-brain barrier penetration, etc. See page 133. Administration of drugs effective for treating Alzheimer's Disease is specifically taught as useful in this manner. See page 137.

It would have been obvious to one of ordinary skill in the art at the time of the invention to administer the composition of Grilli et al. for the treatment of Alzheimer's disease and any neuronal damage associated therewith because (1) Grilli et al. teaches the administration of the composition for said treatment generally; and (2) Bakhshi et al. teaches the administration of drugs to the CNS for the treatment of Alzheimer's Disease via intrathecal catheter. One would have been motivated to administer the composition of Grilli et al. by intraventricular or intrathecal injection, facilitated by catheter, because of an expectation of success in treating neuronal damage associated with Alzheimer's, as taught by Grilli et al. and an expectation of success in alleviating adverse systemic effects associated with the administration of the drug, ensure adequate blood-brain barrier penetration, etc., as taught by Bakhshi et al.

It is noted that the recitation of the limitation of "non-inhibitory of platelets" is a recitation of a limitation as to the property of the drug. It is also noted that the recitation provides no information as to how it would limit the structure of the claimed NSAIDs. Accordingly, since Examiner has shown that it is known to administer the same compositions as instantly claimed, the compositions would obviously be non-inhibitory of platelets. A compound and its properties are inseparable. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Claims 4, 31, 37 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grilli et al. and Bakhshi et al. as applied to claims 1, 5-7, 29, 30, 32-36, 38-40 above, and further in view of McGeer et al. (USPN 5192753).

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Grilli et al. and Bakhshi et al. apply as disclosed above. It is noted that Grilli et al. also teaches that salicylic acid, acetylsalicylic acid, salicylates, etc. and pharmaceutically acceptable salts of acetylsalicylic acid are useful as NSAIDs in the treatments disclosed therein (p 3). The references lack a teaching of choline magnesium trisalicylate.

McGeer et al. teaches arylcarboxylic acids such as salicylic acid, acetylsalicylic acid, choline magnesium trisalicylate, salicylate, etc. as NSAIDs useful for the treatment of Alzheimer's disease (col. 1, lines 36-65).

It would have been obvious to one of ordinary skill in the art to utilize the specific NSAID choline magnesium trisalicylate in a method of Grilli et al. and Bakhshi et al. because (1) Grilli et al. teaches the use of derivatives of acetylsalicylic acid as NSAIDs useful for the treatment of neuronal damage associated with Alzheimer's disease; (2) Grilli et al. teaches that salicylates and pharmaceutical acceptable salts thereof are useful as NSAIDs in the treatment of neuronal damage associated with Alzheimer's disease; and (3) McGeer et al. teaches that choline magnesium trisalicylate is a salicylate suitable for the treatment of Alzheimer's disease. One would have been motivated to utilize the specific salicylate choline magnesium trisalicylate because of the expectation of success in treating neuronal damage associated with Alzheimer's disease by administering a derivative of acetylsalicylic acid to a patient in need thereof, as taught by Gilli et al.

Response to Arguments

Applicant's arguments with respect to the 35 USC 103 rejection of the pending claims have been considered but are moot in view of the new ground(s) of rejection.

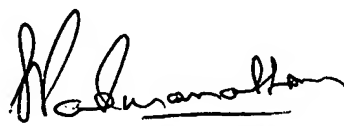
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER